

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0210]

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Publication Date	9-28-05
Officer	A. Corbin

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Veterinary Feed Directive—21 CFR Part 558 (OMB Control Number 0910–0363)—Extension

With the passage of the Animal Drug Availability Act (ADAA), Congress enacted legislation establishing a new class of restricted feed use drugs called Veterinary Feed Directive, which can be distributed without involving State pharmacy laws. Although controls on the distribution and use of VFD drugs are similar to those for prescription drugs regulated under section 503(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(f)), the implementing VFD regulation under 21 CFR 558.6 is tailored to the unique circumstances relating to the distribution of medicated feeds. The content of the VFD is spelled out in the regulation. All distributors of medicated feeds containing VFD drugs must notify FDA of their intent to distribute, and records must be maintained of the distribution of all medicated feeds containing VFD drugs. The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible.

In the **Federal Register** of June 10, 2005 (70 FR 33907), FDA published a 60-day notice soliciting comments on this collection of information. In response to this notice, no comments were received.

The respondents for VFD drugs are Veterinarians, distributors of animal feeds containing VFD drugs, and clients utilizing medicated feeds containing VFD drugs.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
558.6(a)(3) through 558.6(a)(5)	15,000	25	375,000	0.25	93,750
558.6(d)(1)(i) through 558.6(d)(1)(iii)	1,500	1	500	0.25	125
558.6(d)(1)(iv)	20	1	20	0.25	5
558.6(d)(2)	1,000	5	5,000	0.25	1,250
514.1(b)(9)	1	1	1	3.00	3
Total Hours					95,133

¹There are no capital costs or operating and maintenance cost associated with this collection of information

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
558.6(c)(1) through 558.6(c)(4)	112,500	10	1,125,000	.0167	18,788
558.6(e)(1) through 558.6(e)(3)	5,000	75	375,000	.0167	6,263
Total Hours					25,051

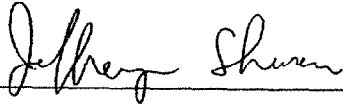
¹There are no capitals cost or operating and maintenance cost associated with this collection of information.

The estimate of the times required for record preparation and maintenance is based on agency communication with industry. Other information needed to calculate the total burden hours are derived from agency records and experience.

SEP 22 2005

Dated: _____

September 22, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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